

Applicants: William C. Olson and Paul J. Maddon  
Serial No.: 10/763,545  
Filed : January 23, 2004  
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**REMARKS**

Claims 109-143 are pending in this application. Applicants have herein amended claim 110 to more clearly define the claimed subject matter and amended claims 118, 119, 121, 122, 131, 132, 134, and 135 to correct dependencies. Applicants have also added new claims 141-143. Support for amended claim 110 may be found, *inter alia*, in the specification at page 15, lines 5-6, page 17, lines 20-24, page 22, lines 16-24, page 23, lines 15-17 and 22-25. Support for new claims 141-143 may be found, *inter alia*, in the specification at page 22, lines 28-30. Applicants maintain that no issue of new matter is raised by this Amendment. Accordingly, claims 109-140, as amended, and new claims 141-143 will be pending in the subject application upon entry to this Amendment.

**Restriction Election:**

On page 2 of the July 26, 2006 Office Action, the Examiner acknowledged applicants' restriction election of Group II drawn to a composition of previously pending claims 99-108 which correspond to pending claims 109-126. The Examiner indicated that the restriction has been made final because applicants did not distinctly point out the supposed errors in the restriction requirement. The Examiner also indicated that since the composition of claims 109-126 has been found to be free of the prior art, new claims 127-140 of Group I drawn to the method of using the composition of Group II have been rejoined. Accordingly, the Examiner indicated that claims 109-140 are pending and examined in the July 26, 2006 Office Action.

**Rejection Under 35 U.S.C. §112, Second Paragraph:**

The Examiner rejected claim 110 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, and without conceding the correctness of the Examiner's

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ground of rejection, applicants note that claim 110 has been amended hereinabove to recite that "the monoclonal antibody or the fragment of such antibody comprises complementarity determining regions (CDRs)". Accordingly, applicants maintain that amended claim 110 complies with the requirements of 35 U.S.C. §112, second paragraph, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Rejection Under 35 U.S.C. §112, First Paragraph:**

The Examiner rejected claims 109-140 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention. Specifically, the Examiner stated that the invention employs a monoclonal antibody against CCR5 and stated that applicants have not deposited the hybridoma cells producing the CCR5 antibodies and that it is not apparent if the hybridoma cells are readily available to the public. The Examiner also stated that the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the hybridoma cells. The Examiner further stated that if a deposit is made under the terms of the Budapest Treaty, a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon issuance of the patent, would satisfy the deposit requirement made therein.

In response, applicants point out that, as stated on page 13, line 34 to page 14, line 8 of the instant specification, the hybridoma cell line designated PA14 was deposited pursuant to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection (ATCC), 10801 University Boulevard Manassas, VA 20110-2209 under ATCC Accession No. HB-12610. Applicants attach hereto as **Exhibit 1** a copy of the Budapest Treaty Deposit Receipt and Viability Statement for the hybridoma cell line designated

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PA14 (ATCC Accession No. HB-12610).

In addition, applicants' undersigned attorney confirms that subject to 37 C.F.R. §808(b), all restrictions on the availability to the public of ATCC No. HB-12610 will be irrevocably removed upon issuance of a U.S. Patent from the subject application and the PA14 deposit will be replenished if necessary during the term of such patent.

In view of the above remarks, applicants maintain that the requirements of 35 U.S.C. §112, first paragraph, have been met and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Provisional Double Patenting Rejections:**

The Examiner provisionally rejected claims 109-126 on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-5, 18, 31, and 74 of copending allowed application U.S. Serial No. 10/371,483. Specifically, the Examiner stated that the allowed claims of this copending application are drawn to a humanized version of mouse anti-CCR5 antibody PA14 with the same CDRs and designated PRO140 in the specification. The Examiner further stated that the subject matter of both sets of claims are not patentably distinct from each other, and therefore the instant claims 109-126 are anticipated by allowed claims 1-5, 18, 31, and 74 of copending U.S. Serial No. 10/371,483.

The Examiner also provisionally rejected claims 127-140 on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-13 and 19-21 of U.S. Patent No. 7,060,273. Specifically, the Examiner stated that claims 1-13 and 19-21 of U.S. Patent No. 7,060,273 are drawn to a method of reducing HIV-1 viral load in an HIV-1 infected subject which comprises administering to the subject solely post-infection an effective viral load-reducing amount of an agent which comprises a CDR domain of an anti-CCR5 antibody, which agent is monoclonal antibody PA14 (ATCC No. HB-12610) or a

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fragment or derivative with the same CDRs. The Examiner further stated that since the method of U.S. Patent No. 7,060,273 encompasses the instant method of treating a subject infected with HIV-1 using the same product, instant claims 127-140 are anticipated by claims 1-13 and 19-21 of U.S. Patent No. 7,060,273.

In response, but without conceding the correctness of the Examiner's grounds of rejection, applicants submit as **Exhibit 2** attached hereto a copy of a signed Terminal Disclaimer relative to U.S. Serial No. 10/371,483, now allowed, and U.S. Patent No. 7,060,273. In accordance with 37 C.F.R. §1.321(c), a sixty-five dollars (\$65.00) fee as set forth in 37 C.F.R. §1.20(d) is required, and a check including this amount is enclosed. Accordingly, applicants maintain that the Examiner's ground for rejection under the nonstatutory obviousness-type double patenting rejections are now moot, and request that this ground of rejection be withdrawn.

**Conclusion**

In view of the remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the grounds of rejection set forth in the July 26, 2006 Office Action, and request allowance of claims 109-140 as amended and pending in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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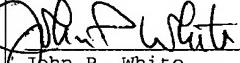
No fee, other than the \$65.00 fee for filing a Terminal Disclaimer and \$75.00 fee for extra claims, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
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 10/26/06  
John P. White Date  
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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

**INTERNATIONAL FORM**

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.**

To: (Name and Address of Depositor or Attorney)

Progenics Pharmaceuticals, Inc.  
Attn: Kathryn M. Brown, Ph.D.  
777 Old Saw Mill River Road  
Tarrytown, NY 10591

Deposited on Behalf of: Progenics Pharmaceuticals, Inc.

**Identification Reference by Depositor:**

**Patent Deposit Designation**

Humanized mouse antibody sequence in DNA plasmid pVK: HuPRO140-VK	PTA-4097
Humanized mouse antibody sequence in DNA plasmid pVg4: HuPRO140 HG2-VH	PTA-4098
Humanized mouse antibody sequence in DNA plasmid pVg4: HuPRO140 (mul B+D+I)-VH	PTA-4099

The deposits were accompanied by: a scientific description, a proposed taxonomic description indicated above. The deposits were received February 22, 2002 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

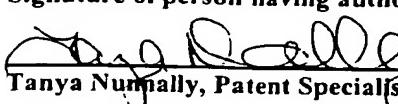
If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested March 18, 2002. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

  
\_\_\_\_\_  
Tanya Nurnally, Patent Specialist, ATCC Patent Depository

Date: March 4, 2005

cc: John P. White  
(Ref: Docket or Case No. 57906-B)

*3/04/05*  
Date 3/04/05

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